Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12990

0 - FRONT

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

Page CFSAN

Form Approved OMB No 0910-0291 Expires 12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 85635

12990

A. Patient information

1 Patient identifier: In confidence

2 Age at time of event: 44 or Date of birth: [redacted]

3 Sex: [X] female [ ] male

4 Weight: 150 lbs or ____ kgs

B. Adverse event or product problem

1. [ ] Adverse event and/or [X] Product problem (e g , defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply)

- [ ] death ____ (mo/day/yr)
- [ ] life-threatening
- [ ] hospitalization – initial or prolonged
- [ ] disability
- [ ] congenital anomaly
- [ ] required intervention to prevent permanent impairment/damage
- [X] other Was Sick

3 Date of event (mo/day/yr): Oct. 20 97

4 Date of this report (mo/day/yr): Oct. 31 97

5 Describe event or problem

I wanted to loss Weight I asked [redacted] Weight How she lost Weight. she told she is member of Herbalife and she is taking it and This how she lost Weight I belived her. she ~~encouraged~~ encouraged me to Joine the co. to Supply My self. she told me this is how to get it - When she felt the form she Put her hasband name and address a man I never met Or know up today after a month I Was very sick throwing out and Headic I did, told her she said Was Normal !! ~~I feed~~ felt

6 Relevant tests/laboratory data, including dates

Headic dizzy very sick and ~~to~~ throwing out. When I stopped taking Herbalife taplets all these sebtome stopped

7 Other relevant history, including preexisting medical conditions (e g , allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)

REC'D.
JUN 26 1998
MEDWATCH CTU

RECEIVED CLINICAL RESEARCH REVIEW/OSN HFS '98 JUL 21 A7

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)

#1 CHINESMA HUNG, BLADDERWRACK, YERBA

#2 MATE VALERAN ROOT PURPLE W. ...

2. Dose, frequency & route used

#1 4 different tablets

#2 twice a day

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 ____

#2 ____

4 Diagnosis for use (indication)

#1 over Weight

#2 ____

5 Event abated after use stopped or dose reduced

#1 [ ] yes [ ] no [ ] doesn't apply

#2 [ ] yes [ ] no [ ] doesn't apply

6 Lot # (if known)

#1 04 7212, 06133

#2 037205, 07180

7 Exp. date (if known)

#1 unknown

#2 ____

8 Event reappeared after reintroduction

#1 [ ] yes [ ] no [ ] doesn't apply

#2 [ ] yes [ ] no [ ] doesn't apply

9 NDC # (for product problems only)

10 Concomitant medical products and therapy dates (exclude treatment of event)

stopped taking the Product the Headic and sickness including to throwing up stopped.

Not sure what name to ...

D. Suspect medical device

1 Brand name: Fumitory Herb - PAPAIN AND Coating color FD&C Blue #1 LAKE for Green tablets do not say How Much ? Thermojetics ELEUTHEROCOCCUS Senticosis ASTRAGALUS, MEMBRANACEOUS smilax Mushroom Bupleurum Capsicum, Chinese CRUCIFEROUS CONCENTRATE, LIGUSTRUM LUCIDUM SILYBUM MARIANUM AND REHMANNIA GLUTINOSA. HAWTHORN BERRY ALFALFA, PARSLEY, MARSHMALLOW Root UVA URSI, CORNSILK, MAGNOLIA Bark Fennel seed ASTRAGALUS BAI CHI, PFAFFIA PANICULATA, PAO D'ARCO, GOLDEN ROD AND LICORICE and More I can not find how many mg each

2 Type of device

3 Manufacturer name & address

6 model # / catalog # / serial # / lot # / other #

9 Device available for evaluation? [ ] yes [ ] no [ ] returned to manufacturer on ____ (mo/day/yr)

10 Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1 Name, address & phone #

RECEIVED JUL 0 ? 1998

000001

2 Health professional? [ ] yes [ ] no

3 Occupation: House

4 Also reported to

- [X] manufacturer
- [ ] user facility
- [X] distributor

5 If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. [ ]

Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

85635

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.